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AND SRI LANKA

February 10, 2021

VIA ECF

The Honorable Karen M. Williams
United States Magistrate Judge
United States District Court - District of New Jersey
Mitchell H. Cohen U.S. Courthouse
4th & Cooper Streets, Room 2060
Camden, New Jersey 08101

The Honorable Thomas I. Vanaskie (Ret.)
Special Master for Discovery
Stevens & Lee
1818 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

**Re: In re Valsartan, Losartan, and Irbesartan Products Liability
Litigation**

Dear Judge Williams and Judge Vanaskie:

The Manufacturer Defendants submit this reply brief in further support of their Motion to Quash Plaintiffs' third party subpoenas on the grounds that, *inter alia*, the Manufacturer Defendants cannot be compelled to accept service of those subpoenas on behalf of the third parties, nor can they be compelled to obtain

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information from those third parties in the absence of service of the subpoenas on the third parties themselves.

INTRODUCTION

The Court should not ignore the requirements of Rule 45 and the Hague Evidence Convention because Plaintiffs have chosen not to attempt to satisfy them. Having failed to serve subpoenas on the foreign third parties, Plaintiffs bear the heavy burden of demonstrating that the Manufacturer Defendants are somehow in the possession, custody, or control of information in the foreign third parties' possession, but the evidence adduced does not satisfy this standard. Accordingly, the Court should deny Plaintiffs' request for the Court to order the Manufacturer Defendants to accept service of and to respond to the unserved foreign third party subpoenas on behalf of, or in place of, the third parties.

ARGUMENT

I. Plaintiffs Cannot Circumvent the Subpoena Process or the Hague Convention for the Sake of Expediency

Plaintiffs assert that they should not be required to satisfy the requirements of Rule 45 and the Hague Evidence Convention because of the "protracted nature of this form of service." [ECF No. 824](#) at 5. Plaintiffs maintain that proper service is not

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required because it would be the “functional equivalent to the Court barring Plaintiffs from obtaining these documents entirely” due to the current discovery deadlines. [ECF No. 824](#) at 5. However, the requirements of service under Rule 45 and the Hague Evidence Convention do not give way simply because of discovery deadlines. Where, as here, the third parties are: (1) foreign corporations; (2) have not voluntarily subjected themselves to the discovery process; and (3) are not otherwise subject to the jurisdiction of the Court, the requirements of Rule 45 and the Hague Evidence Convention must be satisfied. *See* FED. R. CIV. P. 45; *Abbott Labs. v. Impax Labs., Inc.*, No. Civ.A. 03–120–KAJ, 2004 WL 1622223, at *2 (D. Del. July 15, 2004).

II. Plaintiffs Have Not Demonstrated The Manufacturer Defendants Have A Legal Right to Demand Information From The Third Parties

To determine whether a party has sufficient possession, custody, or control to compel production of documents in the possession of another party, the Third Circuit has adopted the “legal right” standard, not a “practical ability” standard as Plaintiffs propose. Specifically, courts in the Third Circuit have established that “control is the test with regard to the production of documents [and] is defined not only as possession, **but as the legal right to obtain the documents requested on demand.**”

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Gerling Intern'l Ins. Co. v. C.I.R., 839 F.2d 131, 140 (3d Cir. 1988) (quoting *Searock v. Stripling*, 736 F.2d 650, 653 (11th Cir. 1984)) (emphasis added); *see also In re Grand Jury*, 821 F.2d 946, 951 (3d Cir. 1987) (“A party’s lack of possession or legal control over documents requested by a subpoena is normally a valid defense to a subpoena and justification for a motion to quash.”); *A First Co., Ltd. v. Worldwide Sourcing LLC*, CIVA09-CV-6003(DMC), 2010 WL 1530785, at *1 (D.N.J. Apr. 15, 2010) (“Control is defined as the legal right to obtain the documents required on demand.”); *Power Integrations, Inc. v. Fairchild Semiconductor Int’l., Inc.*, 233 F.R.D. 143, 146 (D. Del. 2005) (defining control as the legal right to obtain documents as opposed to the broader practical ability standard followed by other circuits); *In re Novartis and Par Antitrust Litig.*, No. 2:19-MC-00149, 2019 WL 5722055 (E.D. Pa. Nov. 5, 2019) (same); C. Wright & A. Miller, 8 Federal Practice & Procedure § 2210 (“Control is defined . . . as the legal right to obtain the documents required on demand”). Plaintiffs have failed to produce evidence to show that the Manufacturer Defendants, by virtue of their relationships with the third parties at issue, have the legal right to obtain documents from them upon demand.

Plaintiffs rest their assertion that the applicable test for control of documents is “practical ability” based on a misreading of a single district court decision. *See*

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Dartell v. Tibet Pharm., Inc., CV 14-3620 (JMV), 2016 WL 11653632, at *2 (D.N.J. Feb. 29, 2016). Although Plaintiffs assert that this case espouses a test for control based upon access and ability to obtain documents rather than a legal right to obtain the documents, *see* [ECF No. 824](#) at 4, the portion of the opinion quoted by Plaintiffs was mere *dicta* summarizing the broader standard for control applied in the Second Circuit. *See Dartell*, 2016 WL 11653632, at *2. Critically, the court in *Dartell* followed its summary of the broader “practical ability” standard for control by concluding that it was ***declining to apply*** the broader definition of control that would also include an inquiry into the practical ability of the subpoenaed party to obtain documents. *Id.* (citing *Cradle IP LLC v. Texas Instruments, Inc.*, 2013 WL 1794992, at *1 (D. Del. Apr. 29, 2013)). The court in *Dartell* ultimately adopted the stricter “legal right” standard over the practical ability standard, denied the plaintiff’s motion to compel, and granted defendant’s motion to quash Rule 45 subpoenas because the defendants did not have possession, custody or control of the foreign entity’s documents.

Furthermore, the cases Plaintiffs have cited in support of their efforts to establish the Manufacturer Defendants’ control over the third parties’ documents are inapposite. In *Moretti*, the Court permitted the plaintiff’s subpoenas where the

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defendants had entered into contracts with their Mexican licensees *with express provisions allowing defendants to inspect/examine licensees' records*. See *Moretti v. Hertz Corp.*, No. CV 14-469-LPS, 2018 WL 4693473, at *2 (D. Del. Sept. 30, 2018), cited at [ECF No. 824](#) at 3. The license agreements between the parties included a clause allowing defendants “to inspect the premises, records, and vehicles of the Licensee” and “to examine Licensee's records ascertaining and verifying the number of vehicles owned, leased, used or kept by the Licensee” *Id.* Thus, in *Moretti*, the “plain language of the agreement” showed that defendants “had the legal right or ability to obtain the documents . . . upon demand.” *Id.*

Similarly, the *Afros* decision does not support Plaintiffs’ argument. See *Afros S.P.A. v. Krauss-Maffei Corp.*, 113 F.R.D. 127, 130 (D. Del. 1986), cited at [ECF No. 824](#) at 3-4. In *Afros*, the court granted plaintiff’s subpoena to defendant’s German parent corporation based on an assessment factors including corporate structures, connection to the transaction, and benefit of the award. *Id.* The analysis in *Afros* is, therefore, inapplicable to the majority of third parties subpoenaed by Plaintiffs, who share no common ownership with the Manufacturer Defendants. Furthermore, as described more fully in the ZHP section below, the reasoning in *Afros* that a subsidiary party to litigation can be compelled to produced documents belonging to

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its parent non-party based on the “very close” relationship between the corporate entities is also factually distinguishable and does not support Plaintiffs’ argument that ZHP is in possession of documents belonging to its subsidiary, Linhai Huanan Chemical Co. Ltd. (“Linhai”) because ZHP and Linhai operate as distinct and separate entities.

Thus, there is no real dispute about the applicable standard for possession, custody, or control. It is the legal right standard. And, as set forth below, Plaintiffs fail to establish that any of the Manufacturer Defendants have a legal right to demand the subpoenaed information from the third parties, and consequently fail to satisfy their burden of demonstrating that the Manufacturer Defendants have possession, custody, or control of the information sought by the subpoenas.

A. ZHP Does Not Have the Legal Right to Demand Information from the Third Parties Identified by Plaintiffs

The ZHP Parties have gone out of their way to demonstrate to Plaintiffs that they do not have the legal right to demand information from four foreign third parties Plaintiffs: Azbil Telstar Technologies (“Azbil”); Chemo Group India; VXL Life Sciences (“VXL”), and Linhai. Yet Plaintiffs refuse to accept the ZHP Parties’ representations at face value, instead baselessly asserting the ZHP Parties are

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“skirt[ing] their discovery obligations” and that Plaintiffs have been “frustrated by Defendants’ repeated refusal to produce contractual documents within their own possession[.]” [ECF No. 824](#) at 3. The contractual documents that Plaintiffs demand do not exist.

In addition, the authority that Plaintiffs cite in their Opposition Brief is either inapplicable or unpersuasive as applied to Azbil, Chemo Group India, VXL, and Linhai. First, Plaintiffs’ reliance on *Moretti* is misplaced as none of these entities are licensees of ZHP and therefore there are no licensing agreements granting ZHP the legal right to obtain the third parties’ documents upon demand. *See* 2018 WL 4693473, at *2, *supra* at 6-7. Second, Plaintiffs’ reliance on *Dartell* and *Afros* is inapplicable to Azbil, Chemo Group India, and VXL as both of these cases concern the issue of possession, custody or control of documents belonging to either a parent company or its subsidiary. ZHP does not have any corporate affiliation or common ownership with Azbil (a third party auditor), Chemo Group India, or VXL (both API customers), and, therefore, the courts’ analysis of the corporate relationships and interactions between a parent and its subsidiary in *Dartell* and *Afros* have no bearing whatsoever on the determination of whether a legal right to demand production of

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documents has been conferred upon ZHP by virtue of ZHP's commercial relationships with these third parties.

While Linhai is a subsidiary of ZHP, Plaintiffs' reliance on *Dartell* and *Afros* with respect to Linhai is also unpersuasive. In *Dartell*, the court quashed Plaintiff's subpoena to a non-party U.S. bank seeking documents held by its Hong Kong affiliate, finding "separate and distinct corporate entities are not readily disregarded, 'except in rare circumstances.'" *Dartell*, 2016 WL 11653632, at *2. Other than identifying the Hong Kong affiliate as a corporate subsidiary, the court concluded Plaintiffs did not demonstrate the "rare circumstances" capable of disregarding the separate and distinct corporate identity of the parent corporation. *See id.* at *4. Likewise, Plaintiffs' only argument that ZHP has control of Linhai's documents is that Linhai is a subsidiary of ZHP. As in *Dartell*, Plaintiffs have failed to point to any agreement between the entities conferring on ZHP the right to demand and inspect documents or explain what circumstances exist in this case to justify disregarding the separate and distinct corporate formalities that exist between ZHP and Linhai. *See id.* at *3-4.

Similarly, the *Afros* decision does not support Plaintiffs' argument. As described above, in *Afros*, the court granted the plaintiff's subpoena to defendant's

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German parent corporation based on an assessment of factors including corporate structures, connection to the transaction, and benefit of the award. *See* 113 F.R.D. at 130. In granting plaintiff's subpoena, the court in *Afros* noted that the corporate relationship between the parent and its subsidiary was "very close." *Id.* at 132. Here, however, although Linhai is a subsidiary of ZHP, it remains a separate and distinct corporate entity and does not operate with ZHP "as one" corporation. *See id.* at 131. And, unlike the subpoenaed entity in *Afros*, Linhai is not a party to this litigation and does not stand to reap any benefit of an award in this lawsuit. *See id.* at 132. Thus, ZHP does not have the legal right to demand Linhai's documents to respond to Plaintiffs' third party subpoena directed to Linhai.

1. The ZHP Parties Do Not Have a Legal Right to Obtain Information from Azbil

Azbil is a facilities auditor that was retained by certain ZHP customers to audit ZHP's facilities. ZHP does not conduct business with Azbil. Because ZHP's customers retained Azbil, **ZHP does not have any agreement with Azbil.** *See* Herrold Declaration ¶¶ 9, 12. The only document connecting ZHP with Azbil is a Letter of Authorization, which authorized Azbil to share the results of certain audits related to cGMP under the European Medicines Requirements it performed with the

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customers who hired Azbil. *Id.* ZHP has directed Plaintiffs to two different examples of these Letters of Authorization, which contain no terms or provisions conferring any right upon ZHP to demand documents from Azbil. See [Ex. F to 1/20/21 Ltr. Brief](#) and Ex. A attached hereto.

Plaintiffs acknowledge and do not dispute the nature of ZHP's relationship with Azbil, but they nevertheless assert in conclusory fashion that "ZHP has the ability to obtain the documents sought by Plaintiffs' subpoena to Azbil, and they should be compelled to produce them." [ECF No. 824](#) at 5. These assertions do not come close to meeting Plaintiffs' burden of showing that ZHP has a legal right to obtain Azbil's documents. It strains credibility to imagine how ZHP could accept service and respond on behalf of Azbil. ZHP has not entered into any agreement with Azbil, let alone an agreement that provides ZHP the authority to demand Azbil's documents for the purposes of complying with or responding to an unserved subpoena directed to Azbil. See Herrold Declaration ¶ 12.

2. The ZHP Parties Do Not Have a Legal Right to Obtain Information from Chemo Group India

ZHP sold various types of API to Chemo Group, presumably the parent company of Chemo Group India. However, ZHP does not have any contracts related

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to Chemo Group India. *See* Herrold Declaration ¶¶ 9, 12. Unable to point to any evidence of a legal right for ZHP to obtain documents from Chemo group, Plaintiffs instead argue that “it is absurd on its face to argue that ZHP does not have the practical ability to obtain documents from [Chemo Group India].” [ECF No. 824](#) at 5. However, Plaintiffs’ labeling something as “absurd” does not make it any less true. And, without any agreement including a right to obtain documents from Chemo Group India, ZHP is not obligated to, and indeed is not able to, produce documents from Chemo Group India.

3. The ZHP Parties Do Not Have a Legal Right to Obtain Information from VXL

Plaintiffs’ argument as to VXL is no different. [ECF No. 824](#) at 5. While it may seem “absurd” to Plaintiffs that an agreement conferring on ZHP the legal right to obtain information from VXL does not exist, the fact remains that such agreement does not exist. VXL purchased valsartan API from ZHP. ZHP did not have a written agreement with VXL, and VXL made its purchases via purchase order. *See* Herrold Declaration ¶¶ 9, 12. These purchase orders confer no legal right on ZHP to force VXL to provide information in this case. *See* Herrold Declaration ¶¶ 7, 9, 12; *see also* [Ex. H to 1/20/21 Ltr. Brief](#). Accordingly, ZHP has no legal right to obtain

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documents from VXL that are responsive to the subpoena and cannot be expected to produce any such documents.

4. The ZHP Parties Do Not Have a Legal Right to Obtain Information from Linhai

Linhai is a subsidiary of ZHP that supplies raw materials to ZHP. However, Linhai is a separate and distinct entity from ZHP and is not a party to this case. Plaintiffs' rely on *Gerling* for the proposition that ““where the subsidiary was an agent of the parent in the transaction giving rise to the suit’, both the party and non-party had control over each other’s documents.” See [ECF No. 824](#) at 5 (citing *Gerling Int’l Ins. Co. v. Comm’r*, 839 F.2d 131, 140 (3d Cir. 1988)). Not only is the portion of *Gerling* relied upon by Plaintiffs *dicta*, but Plaintiffs’ quotation of *Gerling* is incomplete. The *Gerling* court was addressing a scenario “where the subsidiary was an agent of the parent in the transaction giving rise to the suit ***and in litigating the suit on the parent's behalf.***” *Id.* (emphasis added). Linhai is not litigating this lawsuit on ZHP’s behalf. Linhai is not even a party to this lawsuit. Linhai, like Azbil, Chemo Group India, and VXL has not granted ZHP any authority to demand or invade documents in Linhai’s possession, custody, or control. See Herrold Declaration ¶¶ 9, 13. As set forth above, the mere fact that Linhai is a subsidiary of

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ZHP does not confer on ZHP a legal right to compel information for use in this lawsuit from Linhai. *See Dartell*, 2016 WL 11653632, at *4.

The above legal principles and facts demonstrate that Plaintiffs cannot fill the void of foreign service of the third-party subpoenas with the claim that ZHP has possession, custody or control over the third parties such that ZHP can be ordered to collect and produce documents in the third parties' possession. Plaintiffs have not demonstrated that the purely commercial relationships between ZHP and Azbil, Chemo Group, VXL or Linhai have conferred upon ZHP the legal right to demand production of documents from these third parties. Agreements providing for that authority are not being withheld. They simply do not exist. *See Herrold Declaration ¶¶ 9, 12-13*. Thus, ZHP does not have possession, custody, or control over documents belonging to these third parties.

B. Mylan Cannot Be Ordered to Produce Documents From The Two Third Parties Identified by Plaintiffs

Plaintiffs allege that Mylan has the practical ability to obtain the documents requested by Rule 45 subpoenas directed at two third parties: Snehaa Solvents ("Snehaa") and Lantech Pharmaceutical Ltd. ("Lantech"). Plaintiffs' incorrectly rely upon the "practical ability" standard, which does not require Mylan to produce these

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documents on behalf of a third party. Mylan has already established that it is no longer under contract with Snehaa or Lantech, and has no legal right to obtain the requested documents. Plaintiffs focus on the misguided assertion that FDA guidance on document retention could somehow compel Mylan to produce documents that Mylan does not possess. This argument fails, and Mylan is under no obligation to obtain and produce documents from Lantech and Snehaa.

As discussed above, Plaintiffs' reliance on the practical ability to argue that Mylan has control over Snehaa or Lantech's documents is misplaced because the Third Circuit has adopted the legal right test to establish control over a third party's documents. In addition, as discussed at length in the Defendant's initial brief, Mylan is no longer under contract with either Snehaa or Lantech, and, therefore, has no legal right to obtain the documents sought by Plaintiffs' Rule 45 subpoenas.

Similarly, Plaintiffs' reliance on FDA guidance to create a discovery obligation on the part of Mylan is equally unpersuasive. The relevant FDA guidance on contract provisions reads "[t]he quality agreement should define expectations between the contract facility and the owner to review and approve documents." Plaintiffs assert that the FDA's guidance on document retention policies somehow compels Mylan to produce documents that are not in its possession. This argument

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strains credulity for two reasons. First, the FDA's guidance does not require a manufacturer to include provisions in a quality technical agreement that would compel production of documents in litigation; rather, the FDA merely requires that the parties' expectations concerning document review should be defined. Second, the document provisions contained in the applicable Snehaa and Lantech agreements permitted Mylan to request review of documents concerning batch records only, which is a far more confined scope than the discovery sought in Plaintiffs' subpoenas of these entities.

Mylan has already produced responsive documents already in its possession related to Lantech and Snehaa. The documents at issue here are those solely in possession of Lantech and Snehaa. Mylan has no control over these documents, and has no legal right to obtain them at the present time. The FDA's guidance on document retention has no bearing on Rule 45 discovery, and Mylan's Motion to Quash subpoenas directed at Snehaa and Lantech should be granted.

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C. The Aurobindo Parties Do Not Have Possession, Custody or Control of the Third-Party Documents Subject to Plaintiffs' Subpoenas¹

Plaintiffs' contention that the Aurobindo parties (hereinafter "Aurobindo") produced documents in response to the subpoenas is false. Aurobindo did undertake a document production pursuant to Plaintiffs' Rule 34 requests, and, assumes that Plaintiffs discovered the identity of the third parties while reviewing the same. If Aurobindo had documents that referenced the third parties, and were relevant to the litigation, the Federal Rules of Civil Procedure required their production. Thus the truth is, if Aurobindo had documents that related to these third parties and were relevant then they were produced in response to Plaintiffs' Rule 34 Requests for Production *not* Plaintiffs' Third Party Subpoenas.

Moreover, Plaintiffs' request that Aurobindo provide the Bates numbers for responsive documents is misplaced. Clearly, Plaintiffs are aware of the various services the third parties provided Aurobindo by their recitation of the same. *See* [ECF No. 824](#) at 6. It is difficult to image that Plaintiffs concocted the names of these entities out of thin air, so, one must assume that Plaintiffs discovered these entities

¹ As it pertains to the subpoenas directed to Meridan Consulting and ToxRox Consulting, LLC, the parties have reached an agreement.

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through their review of Aurobindo's Rule 34 document production. Requesting Aurobindo provide Bates numbers to documents that Plaintiffs' have already identified is patently inappropriate.

Furthermore, Aurobindo notes that Plaintiffs have been aware of the names of the third-parties since at least September of 2020, and, *not once prior to two weeks ago* (since making the bald assertion that Aurobindo had possession, custody, and control of the third-parties' documents), requested any contracts, if any exist, between Aurobindo and these entities. This is clearly a last ditch effort to circumvent the procedures set forth in the Hague Convention. Furthermore, Plaintiffs' contention that Aurobindo has possession, custody, and control of these documents begs the question: Why would Plaintiffs' prepare subpoenas in the first place? Rather, if this were the case, Plaintiffs' could have sent a request for these documents four months ago.

D. Torrent Does Not Have Possession, Custody or Control of the Third-Party Documents Subject to Plaintiffs' Subpoenas

Plaintiffs cannot force Torrent to accept service or produce documents on behalf of Sipra Labs Ltd. ("Sipra"). Sipra is a third party with which Torrent merely has a standard commercial relationship. Torrent does not have authority to accept

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service on behalf Sipra, nor does Torrent does not have possession, custody, or control over Sipra's documents. Plaintiffs have not pointed to any agreement or contract between Torrent and Sipra that confers upon Torrent the legal right to obtain documents to respond to a subpoena on Sipra's behalf, nor offered any evidence that Torrent has the "practical ability" to access the documents they are requesting. Nothing in Plaintiffs' opposition changes these facts.

The cases cited by Plaintiffs do not further their cause. Sipra is not a subsidiary of Torrent, nor is it a licensee, so Plaintiffs' reliance on *Moretti*, *Dartell* and *Afro* gets them nowhere. (*See supra* Section 2). And there is a reason that Plaintiffs cannot point to a single case on point. Adopting Plaintiffs' position would lead to an absurd result: any time parties were engaged in a commercial relationship and a lawsuit arose even tangentially related to their relationship, they would automatically be required to accept service and produce documents on each other's behalf. This would impose massive, unprecedented burdens on companies and disincentive businesses from entering into commercial relationships. This is not, and cannot be, the standard under the law.

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CONCLUSION

Therefore, for the foregoing reasons and those asserted in their opening and reply briefs in support of their Motion to Quash or for a Protective Order, as well as those asserted in their Supplemental Letter Brief on January 20, 2021, Defendants respectfully request the Court grant said motion as it applies to the foreign third parties.

Respectfully submitted,

/s/ Seth A. Goldberg
Seth A. Goldberg